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10/583,029	05/10/2007	Toshihiro Takeda	AAO-0278	8844
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RADER FISHMAN & GRAUER PLLC			CHU, KAIYEU K	
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1233 20TH STREET N.W., SUITE 501			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,029	TAKEDA ET AL.	
	Examiner	Art Unit	
	KAIYEU CHU	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 August 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-12 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 15 June 2010 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

1. This office action is in response to the amendment filed on 8/3/2010. The affidavits titled "Exhibit A" and "Exhibit B," both of which were filed on 8/3/2010, have been considered. Independent claims 1 and 7 have been amended. Claims 1-12 are presently pending.

Abstract

2. Applicant's abstract is objected to for using legal phraseology, such as "comprises" (line 2 of the Abstract) and "means" (line 15 of the Abstract), and for exceeding 150 words.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means," "comprises," and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1-2 and 5** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Spearman et al. (US Patent No. 7,331,342 B2).

Regarding claim 1, Fig. 3 of Spearman teaches a humidifying device for humidifying a gas, with the water vapor contained in air, comprising: a hollow fiber bundle (75) formed by bundling a plurality of hollow fibers permeable by water vapor (see column 7, lines 1-7), the hollow fibers being orientated in a direction of a predetermined axis; a housing having an accommodating space for accommodating the hollow fiber bundle therein, and having an introduction port (74) for the gas to be humidified, communicating to bores of the hollow fibers (see column 7, lines 16-19), a discharging port (73) for the gas to be humidified, communicating to the bores of the hollow fibers (see column 7, lines 19-23), an air inlet (71) communicating to a space in the housing external of the hollow fibers (see column 7, lines 23-25) to introduce

atmospheric air (83) (see column 7, lines 34-36), and an air exit (72) communicating to the space in the housing external of the hollow fibers (see column 7, lines 23-25); and blowing means (40) arranged at the air inlet of the housing for introducing the atmospheric air into the housing (see Fig. 2; column 4, line 65 – column 5, line 4), wherein a ratio between a sum of cross-sectional areas of the hollow fibers taken along a plane perpendicular to the axis, and an air passage cross-sectional area, is set within a range from 0.1 to 0.7, the air passage cross-sectional area being obtained by subtracting the sum of cross-sectional areas of the hollow fibers from a cross-sectional area of the space of the housing taken along a plane perpendicular to the axis (although not specifically addressed in the specification of Spearman, the ratio of cross-sectional areas based on Fig. 3 appears to be approximately 8/23, which is within the claimed range). Even if the ratio of cross-sectional areas in the air passage of Spearman is not 8/23, the feature of choosing a particular size of the hollow fibers and of the air passage to result in a ratio of cross-sectional areas of 8/23 is considered as an obvious design choice because it appears that Spearman's device would perform equally well with such a particular ratio.

Regarding claim 2, the ratio of cross-sectional areas based on Fig. 3 of Spearman appears to be approximately 8/23, which is within the claimed range of 0.2 to 0.6.

Regarding claim 5, Spearman teaches that the gas to be humidified is an oxygen-concentrated gas (see column 1, lines 12-16).

7. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Goel (US Publication No. 2004/0115489 A1).

Regarding claim 3, Spearman does not disclose that the hollow fiber is comprised of a polyimide membrane or a polyether-imide membrane. However, Goel teaches that hollow fibers may be formed from polyether-imides or polyimides membranes (see [0054], lines 1-4). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the fiber bundles of Spearman out of a polyimide membrane or a polyether-imide membrane as taught by Goel, as these membranes provide excellent water flux and selectivity for water over any unwanted component, as well as remain stable after continuous long-term operation (see Goel: [0051], lines 1-12).

8. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Daniell et al. (US Patent No. 6,050,260).

Regarding claim 4, Spearman does not teach a humidity sensor provided at the discharging port for detecting the humidity of the gas to be humidified; and a control section for controlling the blowing means to make the humidity of the gas to be humidified, as detected by the humidity sensor, equal to a predetermined value. However, Fig. 1 Daniell teaches a humidity sensor (14) (see column 4, lines 17-19 and 21-24) provided at the discharging port for detecting the humidity of the gas to be humidified (see column 4, lines 6-19); and a control section (9) for controlling the blowing means (15) to make the humidity of the gas to be humidified, as detected by the

humidity sensor, equal to a predetermined value (see column 3, line 66 – column 4, line 6; column 4, lines 25-37). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the oxygen humidifier of Spearman with a humidity sensor at its discharging port and a control section for controlling blowing means as taught by Daniell in order to improve the control the oxygen humidifier of Spearman has over humidification level as desired by the user.

9. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Izumi et al. (US Patent No. 4,453,952).

Regarding claim 6, Spearman teaches an oxygen concentrating system, the system adsorbing nitrogen contained in the air and removing it therefrom to produce an oxygen-concentrated gas for a medical use (see column 4, lines 16-18), and comprising: an oxygen concentrating section of a pressure-swing adsorption type (17, adsorption bed of molecular sieves) (see column 4, lines 14-32); a conduit for introducing the oxygen-concentrated gas produced in the oxygen concentrating section to a user (see column 5, lines 40-42; there must be a conduit in order to deliver the oxygen-enriched gas to the patient); pressure-adjustment means (54) disposed in the conduit for adjusting a pressure at an exit of the oxygen concentrating section to a constant value (see column 5, lines 34-37); flow rate regulating means (57) for regulating a flow rate of the oxygen-concentrated gas flowing through the conduit to a constant value (see column 5, lines 37-40). It is noted that Spearman does not disclose the oxygen concentrating section having a plurality of adsorption columns, the columns

respectively accommodating adsorbents having a selective absorbability for nitrogen. However, Izumi teaches a plurality of adsorption columns (see column 6, lines 28-30) accommodating Na-A adsorbents (see column 5, lines 3-11) that may have a selective absorbability for nitrogen (see column 3, lines 18-23), and also that nitrogen-selective adsorbents such as the molecular sieves "5A" and "13X" are well-known for being employed in processes for the concentration of oxygen by removing nitrogen selectively from air (see column 1, lines 53-59). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the adsorption bed of Spearman to include adsorption columns with nitrogen-selective adsorbents as taught by Izumi in order to provide an alternate way to adsorb nitrogen and produce an oxygen-rich gas.

10. **Claims 7, 9, and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Martinez et al. (US Patent No. 6,582,955 B2).

Regarding claim 7, as the humidification device of Spearman contains only a single fiber bundle, Spearman does not teach that the humidification device comprises a plurality of fiber bundles. However, Martinez teaches a bioreactor using a plurality of hollow fiber bundles (see column 2, lines 60-65). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the humidification device of Spearman to use multiple hollow fiber bundles as taught by Martinez in order to more evenly humidify the dry gas passing through the hollow fibers.

Regarding claim 9, the modified humidification device of Spearman and Martinez does not specify that each of the hollow fiber bundles include 50 to 1000 hollow fibers. However, the optimal number of hollow fibers within a hollow fiber bundle largely depends on the application of the device and the size of the hollow fibers. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include 50 to 1000 hollow fibers in each of the hollow fiber bundles for design choice considerations.

Regarding claim 11, refer to the rejection of claim 5 for reasoning.

11. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Martinez et al. as applied to claims 7,9, and 11 above, and further in view of Goel.

Regarding claim 8, the modified humidification device of Spearman and Martinez does not teach that the hollow fiber is comprised of a polyimide membrane or a polyether-imide membrane. However, Goel teaches that hollow fibers may be formed from polyether-imides or polyimides membranes (see [0054], lines 1-4). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the fiber bundles of the modified humidification device of Spearman and Martinez out of a polyimide membrane or a polyether-imide membrane as taught by Goel, as these membranes provide excellent water flux and selectivity for water over any unwanted component, as well as remain stable after continuous long-term operation (see Goel: [0051], lines 1-12).

12. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Martinez et al. in further view of Daniell et al.

Regarding claim 10, the modified humidification device of Spearman and Martinez does not teach a humidity sensor provided at the discharging port for detecting the humidity of the gas to be humidified; and a control section for controlling the blowing means to make the humidity of the gas to be humidified, as detected by the humidity sensor, equal to a predetermined value. However, Fig. 1 Daniell teaches a humidity sensor (14) (see column 4, lines 17-19 and 21-24) provided at the discharging port for detecting the humidity of the gas to be humidified (see column 4, lines 6-19); and a control section (9) for controlling the blowing means (15) to make the humidity of the gas to be humidified, as detected by the humidity sensor, equal to a predetermined value (see column 3, line 66 – column 4, line 6; column 4, lines 25-37). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified humidification device of Spearman and Martinez with a humidity sensor at its discharging port and a control section for controlling blowing means as taught by Daniell in order to improve the control the modified humidification device of Spearman and Martinez has over humidification level as desired by the user.

13. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Spearman et al. in view of Martinez et al. in further view of Izumi et al.

Regarding claim 12, the modified humidification device of Spearman and Martinez teaches an oxygen concentrating system, the system adsorbing nitrogen contained in the air and removing it therefrom to produce an oxygen-concentrated gas for a medical use (Spearman: column 4, lines 16-18), and comprising: an oxygen concentrating section of a pressure-swing adsorption type (Spearman: 17, adsorption bed of molecular sieves) (Spearman: column 4, lines 14-32); a conduit for introducing the oxygen-concentrated gas produced in the oxygen concentrating section to a user (Spearman: column 5, lines 40-42; there must be a conduit in order to deliver the oxygen-enriched gas to the patient); pressure-adjustment means (Spearman: 54) disposed in the conduit for adjusting a pressure at an exit of the oxygen concentrating section to a constant value (Spearman: column 5, lines 34-37); flow rate regulating means (Spearman: 57) for regulating a flow rate of the oxygen-concentrated gas flowing through the conduit to a constant value (Spearman: column 5, lines 37-40). It is noted that the modified humidification device of Spearman and Martinez does not disclose the oxygen concentrating section having a plurality of adsorption columns, the columns respectively accommodating adsorbents having a selective absorbability for nitrogen. However, Izumi teaches a plurality of adsorption columns (see column 6, lines 28-30) accommodating Na-A adsorbents (see column 5, lines 3-11) that may have a selective absorbability for nitrogen (see column 3, lines 18-23), and also that nitrogen-selective adsorbents such as the molecular sieves "5A" and "13X" are well-known for being employed in processes for the concentration of oxygen by removing nitrogen selectively from air (see column 1, lines 53-59). Thus, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to modify the adsorption bed of the modified humidification device of Spearman and Martinez to include adsorption columns with nitrogen-selective adsorbents as taught by Izumi in order to provide an alternate way to adsorb nitrogen and produce an oxygen-rich gas.

Response to Arguments

14. Applicant's arguments filed 8/3/2010 have been fully considered but they are not persuasive.

15. In the first paragraph on page 9 of the Remarks, Applicant expresses concern as to whether the Spearman reference is properly supported by the Spearman provisional Application. The Examiner asserts that the subject matter relied upon within the Spearman reference to make the rejections detailed in this office action and the prior office action *is* in compliance with 35 U.S.C. 112, first paragraph. Even a cursory glance at Fig. 3 of the Spearman Provisional Application will indicate this conclusion.

16. In the first paragraph on page 10 of the Remarks, Applicant argues that Applicant's claimed invention exhibits *unexpected results* in providing effective humidity in an oxygen concentrated gas, as demonstrated in the declaration under 37 CFR 1.132 filed on 8/3/2010 and titled Exhibit A. Although the Examiner appreciates Applicant's apparently successful results, the Examiner does not share Applicant's view that the claimed ratio range of 0.1 to 0.7 produces unexpected results and is inventive. Furthermore, it is clear to a person of ordinary skill in the art that there is an optimal

ratio range for humidifying gas passing through a hollow fiber. If the ratio is too great (i.e. the hollow fibers have extremely large cross-sectional areas), then there is a dearth of permeable surface area to optimally accommodate all of the oxygen molecules. On the other hand, if the ratio is too low (i.e. the hollow fibers have extremely small cross-sectional areas), then an application of Bernoulli's principle suggests that the oxygen molecules are traveling through the hollow fiber too quickly to absorb an optimal amount of moisture. In order to qualify as *unexpected results*, the results cannot be merely superior or better, but must be surprisingly or *unexpectedly* better than a person of ordinary skill in the art would expect. The Examiner holds the view that the results as demonstrated in Exhibit A are not *unexpectedly* better than a person of ordinary skill in the art would expect and hence not *unexpected results*. Furthermore, a person of ordinary skill in the art at the time of invention seeking to determine the optimal method in humidifying gas passing through hollow fibers would look to varying the ratio of the cross-sectional areas between the hollow fibers and the air passage in the housing; this varying of the ratio would likely include testing the claimed ranges. Thus, the claimed ranges cannot be held as inventive. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; *Allen et al. v. Coe*, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

17. In all four paragraphs on page 13 of the Remarks, Applicant appears to be attacking the Martinez reference as failing to read on Applicant's claimed invention. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Thus, Applicant's arguments regarding the Martinez reference are not germane in overcoming the combination of Spearman and Martinez. In the fourth paragraph on page 13 of the Remarks, Applicant further notes that the declaration under 37 CFR 1.132 filed on 8/3/2010 and titled Exhibit B demonstrates unexpected results of the Applicant's invention that Applicant alleges cannot be demonstrated by Martinez. However, Applicant has not addressed whether the alleged unexpected results of Applicant's invention could or could not be expectedly demonstrated by the combination of Spearman and Martinez. The Examiner holds the view that the combination of Spearman and Martinez *could* demonstrate the results as shown in Exhibit B since the combination of Spearman and Martinez would have a similar structure to Applicant's claimed invention which produced the results shown in Exhibit B. Thus, the rejection stands.

Response to Amendment

18. The declaration under 37 CFR 1.132 filed on 8/3/2010 and titled Exhibit A is insufficient to overcome the rejection of claim 1 based upon Spearman as set forth in

the last Office action because the declaration is not persuasive in proving unexpected results. Please refer to the “Response to Arguments” section above for reasoning.

19. The declaration under 37 CFR 1.132 filed on 8/3/2010 and titled Exhibit B is insufficient to overcome the rejection of claim 7 based upon Spearman in view of Martinez as set forth in the last Office action because the facts presented are not germane to the rejection at issue. Please refer to the “Response to Arguments” section above for reasoning.

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAIYEU CHU whose telephone number is (571)270-5376. The examiner can normally be reached on Monday-Friday 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine R. Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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